

Atty. Dkt. No. 074129-0492

Appl. No. 10/019,786

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## REMARKS

Applicants respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

In the specification, Applicants have amended paragraphs on pages 7, 22, and 39 to address the PTO's objection(s). No new has been added.

## I. CLAIMS STATUS

Claims 1, 6-9, 11-12, 16-17, and 21 are currently amended, and claims 4-5 are canceled without prejudice or disclaimer.

Claim 1 was amended as shown. It is believed that the support for the amendment is obvious from the as-filed specification. The lactic acid homopolymers and salts thereof are described, e.g., at page 14, lines 6-7 of the as-filed specification. No new matter has been added.

Claims 1-3 and 6-23 are pending in the application and stand rejected.

## II. GENERAL COMMENTS

The Examiner is thanked for identifying and considering the counterparts to A1 and A4.

A translation of the priority document into the English language is enclosed, *vide infra*.

## III. SPECIFICATION

The PTO objected to the specification because of improper use of trademarks. As the present specification was amended as shown, this objection should be withdrawn.

## IV. CLAIM OBJECTIONS

The PTO objected to claim 1 for use of parenthesis in the claim. The present version of claim 1 avoids the objection, which should be withdrawn.

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Along these lines, claim 11 was amended, too.

V. REJECTION UNDER 35 U.S.C. § 112, ¶ 1

Claim 21 was rejected as unsupported by an enabling disclosure. Office action, pp. 3-5. The present version of claim 21 reads as follows:

21. A prophylactic or therapeutic agent against prostate cancer, prostate hyperplasia, endometriosis, hysteromyoma, metrofibroma, precocious puberty, dysmenorrhea or mammary cancer or a contraceptive containing a sustained release composition according to claim 3.

According to the Examiner, the following subject matter is enabled by the specification:

agent is a therapeutic agent against prostate cancer,  
therapeutic agent against prostate hyperplasia,  
therapeutic agent against endometriosis,  
therapeutic agent against hysteromyoma,  
therapeutic agent against metrofibroma,  
therapeutic agent against precocious puberty,  
prophylactic or therapeutic agent against dysmenorrhea or  
therapeutic agent against mammary cancer or  
a contraceptive,

but the following subject matter is not:

agent is a prophylactic agent against prostate cancer,  
prophylactic agent against prostate hyperplasia,  
prophylactic agent against endometriosis,  
prophylactic agent against hysteromyoma,  
prophylactic agent against metrofibroma,  
prophylactic agent against precocious puberty, or

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prophylactic agent against mammary cancer.

Office action, p. 3. Applicants respectfully submit that it is believed that the Examiner disagrees that the recited agent (LH-RH derivative) is effective for the recited indications noted above.

Yet the recited agent promotes the secretion of sex hormones as their acute activity, while it suppresses the secretion in their chronic activity (paradoxical effect). So, the recited agent is effective for all the recited indications.

For example, an article by Pereti *et. al.* Clin. Pharmacokinet. 2002; 41(7): 485-504 (enclosed for consideration) explains a functional mechanism for LH-RH (GnRH) derivatives such as leuporelin on pages 487-488. Taking this functional mechanism into consideration, Applicants respectfully submit that one of ordinary skill in the art would consider the claimed agent effective for all the recited indications. Thus, Applicants respectfully submit that the present specification would have enabled the full scope of claim 21.

#### VI. REJECTION UNDER 35 U.S.C. § 112, ¶ 2

Claims 1-22 were rejected as indefinite for reciting "wherein the product of the weight average molecular weight ...." Office action, pp. 5-6. The rejection wanted to know whether or not the end points were embraced. Yes. The term *ranges from a to b* includes the end points *a* and *b* as well as values between the endpoints. As such, the present version of the claims avoids the rejection. Thus, the present rejection should be withdrawn.

Claims 6-7 were rejected as indefinite for reciting "100/0." Office action, p. 6. The present version of the claims avoids the rejection, because claim 1 now recites *a polymer chosen from lactic acid homopolymers and salts thereof and lactic acid-glycolic acid polymers and salts thereof*. Thus, the present rejection should be withdrawn.

Claim 21 was rejected as indefinite for reciting "A prophylactic or therapeutic agent against ... or a contraceptive containing a sustained released composition," because it is unclear whether or not "all family members of the claim contain a sustained released composition." Office action, p. 6. The present ground for rejection is traversed, because it is

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respectfully submitted that the rules of grammar would have allowed one of ordinary skill in the art to have reasonably apprised that the term *containing a sustained release composition*, recited in claim 21, modifies both *prostate cancer, prostate hyperplasia, endometriosis, hysteromyoma, leiomyofibroma, precocious puberty, dysmenorrhea or mammary cancer and a contraceptive*. In view of these comments, it is respectfully submitted that the present version of the claim avoids the rejection. Thus, the present rejection should be withdrawn.

VII. REJECTION UNDER 35 U.S.C. § 102(a)

Claims 1-23 stand rejected as anticipated by HATA (JP 11-269094). Applicants respectfully traverse the rejection.

Applicants note that a publication date of HATA is October 10, 1999, which is after July 15, 1999, a foreign priority date of the present application. To antedate HATA, enclosed with this paper are an English Language Translation of Japanese Application No. JP 1999-201887, to which the instant application claims priority, and a verification of English Language Translation by Matsuo Tanaka. It is submitted that each pending claim is fully supported by JP1999-201887.

Because HATA was published after the effected date of the rejected claims, HATA is not evidence of a prior invention as to any of the instant claims. Thus, Applicants respectfully request withdrawal of the rejection.

VIII. REJECTION UNDER 35 U.S.C. § 102(a)

Claims 1-23 were rejected as anticipated by Saikawa (US 6,740,634). Applicants respectfully traverse.

Applicants note that Saikawa issued from US application No. 09/582,926, the national stage of PCT/JP99/00086, filed January 13, 1999, which international application published as WO99/36099 in Japanese on July 22, 1999. Because PCT application No. PCT/JP99/00086 was filed prior to November 29, 2000, the § 102(c) date of Saikawa is July 5, 2000, the date § 371(c)(1), (2) & (4) were satisfied. The § 102(a) publication date of Saikawa is July 22, 1999, a date of WO99/36099 publication (the publication date of the

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Japanese priority document is unknown). Since both July 5, 2000, and July 22, 1999 are after July 15, 1999, the effected filing date of the claims of the present application, Saikawa is not evidence of a prior invention against the instant claims. Thus, the present rejection should be withdrawn.

#### IX. DOUBLE PATENTING

Claims 1-15 and 20-23 stand rejected on the ground of non-statutory double patenting over claims 1-18 of Saikawa (US 6,740,634).

What is claimed is:

1. A sustained-release composition comprising a biologically active peptide, hydroxyaphthone acid or salt thereof, and a biodegradable polymer or salt thereof,
2. A sustained-release composition according to claim 1 wherein the biologically active peptide is an LH-RH derivative,
3. A sustained-release composition according to claim 1 wherein the hydroxyaphthone acid is 3-hydroxy-2-naphthoic acid,
4. A sustained-release composition according to claim 1 wherein the biodegradable polymer is an  $\alpha$ -hydroxy-carboxylic acid polymer,
5. A sustained-release composition according to claim 4 wherein the  $\alpha$ -hydroxy-carboxylic acid polymer is a lactic acid-glycolic acid polymer,
6. A sustained-release composition according to claim 5 wherein the content ratio of lactic acid and glycolic acid is 10:90 to 40:60 mol %,
7. A sustained-release composition according to claim 6 wherein the content ratio of lactic acid and glycolic acid is 10:90 mol %,
8. A sustained-release composition according to claim 3 wherein the weight-average molecular weight of the polymer is about 2,000 to about 100,000,
9. A sustained-release composition according to claim 8 wherein the weight-average molecular weight of the polymer is about 20,000 to about 50,000,
10. A sustained-release composition according to claim 2, wherein the LH-RH derivative is SEQ ID NO:1,
11. A sustained-release composition according to claim 5, wherein the terminal carboxyl group content of the polymer is 50-90 mmoles of the polymer,
12. A sustained-release composition according to claim 2, wherein the molar ratio of the hydroxyaphthone acid or salt thereof and the LH-RH derivative or salt thereof is from 3 to 4 to 4 to 3,
13. A sustained-release composition according to claim 12, wherein the LH-RH derivative or salt thereof is contained at 14% (w/w) to 24% (w/w),
14. A sustained-release composition according to claim 1, wherein the biologically active peptide is very slightly soluble in water or soluble in water,
15. A sustained-release composition according to claim 1, which is intended for injection,
16. A method of treating postmenopausal cancer, postmenopausal osteoporosis, endometriosis, hirsutism, menorrhagia, premenstrual syndrome, dyspareunia, or breast cancer, comprising administering a pharmaceutically effective amount of the sustained-release composition according to claim 10 to a mammal in need thereof,
17. A sustained-release composition comprising the hydroxyaphthone acid salt of a biologically active peptide and a biodegradable polymer or salt thereof,
18. A method of reducing fertility comprising administering a pharmaceutically effective amount of the sustained-release composition according to claim 10 to a mammal in need thereof.

\* \* \* \* \*

It is submitted that the present claims avoid this rejection as Saikawa's claims neither describe nor provide the motivation or a reasonable expectation of success to make a product of the weight average molecular weight of said polymer and the amount in  $\mu$ mol of the terminal carboxyl group per unit mass in grams of said polymer ranges from 1,200,000 to 3,000,000. Thus, the present rejection should be withdrawn.

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CONCLUSION


Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By

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## Enclosures:

Pereti *et. al.* Clin. Pharmacokinet. 2002; 41(7): 485-504;  
English Language Translation of Japanese Application No. JP 1999-201887  
(77 pages); and  
Verification of English Language Translation of JP 1999-201887 by Matsuo Tanaka  
(1 page).